510(k) SUMMARY

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CONTACT NAME: Gregory Payne

DATE PREPARED: January 31, 2013

DEVICE TRADE NAME: BD Veritor™ System for Rapid Detection of Group A Strep

DEVICE COMMON NAME: Streptococcus spp. serological reagents

DEVICE CLASSIFICATION: 21 CFR § 866.3740

PREDICATE DEVICES: Clearview Advanced™ Strep A Test

INTENDED USE:

The BD Veritor™ System for Rapid Detection of Group A Strep test is a rapid chromatographic immunoassay for the direct and qualitative detection of Group A Streptococcus antigen from throat swabs of symptomatic patients. It is intended to be used in conjunction with the BD Veritor™ System Reader as an aid in the diagnosis of Group A Strep. All negative test results should be confirmed by bacterial culture because negative results do not preclude Group A Strep infection and should not be used as the sole basis for treatment.

The BD Veritor System for rapid detection of Group A Strep test is intended for use in point-of-care or laboratory settings.

DEVICE DESCRIPTION:

The BD Veritor™ System for rapid detection of Group A Strep is a qualitative, lateral flow immunoassay for the detection of Strep A carbohydrate antigen in a throat swab. In this test, antibody specific to Strep A carbohydrate antigen is coated on the test line region of the Assay device. During testing, the processed throat swab specimen reacts with an antibody to Strep A that is conjugated onto detector particles. The mixture migrates up the membrane to react with the antibody to Strep A on the membrane and is captured by the line of antibody on the membrane. A positive result for Strep A is determined by the BD Veritor ™ System Reader when antigen-conjugate is deposited at the Test "T" position and the Control "C" position on the BD Veritor™ System Strep A assay device.

DEVICE COMPARISON:

The BD Veritor™ System for Rapid Detection of Group A Strep was compared to the Clearview Advanced™ Strep A test k091489.

Product Feature	BD Veritor™ System for Rapid Detection of Group A Strep	Binax Clearview Advanced Strep A test k091489
Intended Use	The BD Veritor™ System for Rapid Detection of Group A Strep test is a rapid chromatographic immunoassay for the direct and qualitative detection of group A *Streptococcus* antigen from throat swab specimens of symptomatic patients to aid in diagnosis of Group A *Streptococcus* infection. It is intended to be used in conjunction with the BD Veritor™ System Reader as an aid in the diagnosis of Group A Streptococcal infection.	The Binax Clearview Advanced™ Strep A test is a rapid chromatographic immunoassay for the qualitative detection of group A *Streptococcus* antigen from throat swab specimens as an aid in the diagnosis of Group A Streptococcal infection.
Specimen Types	Throat swabs	Throat swabs
Assay Technology	Immunochromatographic	Immunochromatographic
Detection Format	An opto-electronic reader determines the line intensity at each of the spatially-defined test and control line positions, interprets the results using the scoring algorithm, and reports a positive, negative, or invalid result on the LCD screen based on pre-set thresholds.	Visual determination of presence or absence of pink-to-red Test Line and the appearance of a blue Procedural Control Line on the test strip indicate the presence of Group A Streptococcal antigen.
Qualitative or Quantitative	Qualitative	Qualitative

Product Feature	BD Veritor™ System for Rapid Detection of Group A Strep	Binax Clearview Advanced Strep A test k091489
Total Assay Time	Approximately 5 minutes	Less than 5 minutes
Control format	• Kit Strep A positive control swab • Kit Strep A negative control swab • Internal control lines	• Kit Strep A positive control swab • Kit Strep A negative control swab
Detection of Group A Strep	Test will indicate the presence of both viable and non-viable group A *Streptococcus* bacteria	Test will indicate the presence of both viable and non-viable group A *Streptococcus* bacteria

SUMMARY OF PERFORMANCE DATA:

Analytical Sensitivity

The limit of detection for *Streptococcus pyogenes* was established with the BD Veritor™ System for Rapid Detection of Group A Strep test. The limit of detection (LOD) is defined as the lowest concentration that produces an approximate 95% positive reaction when tested with 60 replicates.

STRAIN	LOD (CFU/mL)	Results	% Positivity
12384	1×10^5	57/60 Positive	95.0%
19615	5×10^4	58/60 Positive	96.7%
25663	2×10^5	57/60 Positive	95.0%

Analytical Specificity

The reactivity of various Streptococcal strains was determined with the BD Veritor™ System for Rapid Detection of Group A Strep test. Lancefield Groups A, B, C, D, F and G were tested at $1X10^9$ CFU/mL in triplicate and yielded negative results.

Various microorganisms (including bacteria and yeasts) that might be found in specimens were evaluated for potential cross reactivity with the BD Veritor™ System for Rapid Detection of Group A Strep test.

BD Veritor™ System for Rapid Detection of Group A Strep Cross Reactivity Study Results – Bacteria and Yeast		
Microorganism Name	**Concentration Tested**	**Group A Strep Test Result**
Arcanobacterium haemolyticum	$1x10^9$ CFU/mL	Negative
Bordetella pertussis	$5x10^8$ CFU/mL	Negative
Candida albicans	$1.x10^9$ CFU/mL	Negative
Corynebacterium diphtherium sp (Corynebacterium sp)	$1x10^9$ CFU/mL	Negative
Enterococcus faecalis	$1x10^9$ CFU/mL	Negative
Enterococcus faecium	$1x10^9$ CFU/mL	Negative
Escherichia coli	$1.5x10^9$ CFU/mL	Negative
Fusobacterium necrophorum	$1x10^9$ CFU/mL	Negative
Haemophilus influenzae	$1x10^9$ CFU/mL	Negative
Haemophilus parahemolyticus	$1.2x10^5$ CFU/mL	Negative
Haemophilus parainfluenzae	$1x10^9$ CFU/mL	Negative
Klebsiella pneumoniae	$1.5x10^9$ CFU/mL	Negative
Lactobacillus sp (Lactobacillus casei)	$1x10^9$ CFU/mL	Negative
Moraxella catarrhalis	$1x10^9$ CFU/mL	Negative
Moraxella lacunata	$1x10^9$ CFU/mL	Negative
Mycobacterium tuberculosis avirulent	$5x10^6$ CFU/mL	Negative
Neisseria gonorrhoeae	$1x10^9$ CFU/mL	Negative
Neisseria lactamica	$1x10^9$ CFU/mL	Negative
Neisseria meningitidis	$1x10^9$ CFU/mL	Negative
Neisseria mucosa	$1x10^6$ CFU/mL	Negative
Neisseria sicca	$1x10^9$ CFU/mL	Negative
Neisseria subflava	$1x10^9$ CFU/mL	Negative
Proteus vulgaris	$1x10^9$ CFU/mL	Negative
Pseudomonas aeruginosa	$1x10^9$ CFU/mL	Negative
Serratia marcescens	$1x10^9$ CFU/mL	Negative
Staphylococcus aureus	$1x10^9$ CFU/mL	Negative
Staphylococcus epidermidis	$1x10^9$ CFU/mL	Negative
Staphylococcus haemolyticus	$1x10^9$ CFU/mL	Negative
Streptococcus anginosus	$1x10^9$ CFU/mL	Negative
Streptococcus mitis	$1x10^9$ CFU/mL	Negative
Streptococcus mutans ATCC25173	$3x10^9$ CFU/mL	Negative
Staphylococcus oralis	$1x10^9$ CFU/mL	Negative
Streptococcus pneumoniae	$1x10^9$ CFU/mL	Negative
Streptococcus salivarius	$1x10^9$ CFU/mL	Negative

BD Veritor™ System for Rapid Detection of Group A Strep Cross Reactivity Study Results – Bacteria and Yeast		
Microorganism Name	**Concentration Tested**	**Group A Strep Test Result**
Staphylococcus sanguis	$1x10^9$ CFU/mL	Negative
Streptococcus sp. Group B	$1x10^9$ CFU/mL	Negative
Streptococcus sp. Group C	$1x10^9$ CFU/mL	Negative
Streptococcus sp. (bovis II) Group D	$1x10^9$ CFU/mL	Negative
Streptococcus sp. Group F	$1x10^9$ CFU/mL	Negative
Streptococcus sp. Group G	$1x10^9$ CFU/mL	Negative
Yersinia enterocolitica	$1x10^9$ CFU/mL	Negative
Adenovirus Type 1	$1.6x10^6$ $TCID_{50}$ /mL	Negative
Adenovirus Type 7	$2.81x10^5$ $TCID_{50}$/mL	Negative
Cytomegalovirus	$8.9x10^3$ $TCID_{50}$/mL	Negative
Enterovirus (VR-28 Human Coxsackievirus)	$8.9x10^6TCID_{50}$/mL	Negative
Epstein Barr Virus	N/A	Negative
HSV Type 1 (HF)	$8.89x10^6$ $TCID_{50}$/mL	Negative
Human coronavirus OC43	$2.81x10^4$ $TCID_{50}$/mL	Negative
Human metapneumovirus (HMPV-27 A2)	$2.8x10^6$ $TCID_{50}$/mL	Negative
Human parainfluenza	$2.8x10^6$ $TCID_{50}$/mL	Negative
Measles	$1.6x10^4$ $TCID_{50}$/mL	Negative
Mumps virus	$1.6x10^5$ $TCID_{50}$/mL	Negative
Respiratory syncytial virus VR-26	1.6×10^7 $TCID_{50}$/mL	Negative
Rhinovirus	$2.8x10^6$ $TCID_{50}$/mL	Negative

Of the microorganisms tested, none demonstrated cross-reactivity with the BD Veritor™ System for Rapid Detection of Group A Strep test.

Interfering Substances

Various substances were evaluated for potential interference with the BD Veritor™ System for Rapid Detection of Group A Strep test at concentrations comparable to or greater than levels that may be present in patient respiratory samples.

Substance	Concentration Tested	Interference with Group A Result
4-Acetamidophenol	10 mg/mL	No
Acetylsalicylic acid	20 mg/mL	No

Albuterol	0.083 mg/mL	No
Amantadine	500 ng/mL	No
Ascorbic acid chewable tablets	5% by weight	No
Beclomethasone	500 ng/mL	No
Benzocaine throat spray (Cepacol)	5% by volume	No
Blood, type A	2% (v/v)	No
Blood, type B	2% (v/v)	No
Blood, type AB	2% (v/v)	No
Blood, type O	2% (v/v)	No
Budesonide	500 ng/mL	No
Chlorpheniramine maleate	5 mg/mL	No
Dexamethasone	10 mg/mL	No
Dextromethorphan (10 mg/mL)	10 mg/mL	No
Dyclonine HCl lozenges (Sucrets)	5% w/v	No
Diphenhydramine HCl	5 mg/mL	No
Fexofenadine	500 ng/mL	No
FluMist	1% v/v	No
Fluticasone	500 ng/mL	No
Guaiacol Glyceryl Ether	20 mg/mL	No
Ibuprofen	10 mg/mL	No
Loratidine	100 ng/mL	No
Menthol Throat Lozenges	5% w/v	No
Mometasone	500 ng/mL	No
Mouthwash (at 5% by volume) Listerine	5% (v/v)	No
Mouthwash Scope	5% v/v	No
Mouthwash CVS	5% v/v	No
Mucin, salivary protein, purified	1 mg/mL	No
Nasal Spray	5% v/v	No
Nasal Spray	5% v/v	No
Nasal Spray	5% v/v	No
Oseltamivir	500 ng/mL	No
Oxymetazoline	0.05 mg/mL	No
Phenol throat spray (Chloraseptic)	5% v/v	No
Phenylephrine	1 mg/mL	No
Pseudoephedrine HCl	20 mg/mL	No
Throat drops: CVS	5% w/v	No
Throat drops: Pedia Care	5% w/v	No
Throat drops: Triaminic	5% w/v	No
Tobramycin	500 ng/mL	No
Triamcinolone	500 ng/mL	No
Zanamivir	1 mg/mL	No
Zicam throat spray (Zn /	5% v/v	No

benzalkonium chloride)		
Zinc Lozenges	5% w/v	No

Of the substances tested in this study, none exhibited interference when either Group A positive or Group A negative samples were tested with the BD Veritor™ System for Rapid Detection of Group A Strep test.

Media Compatibility

Various types of transport media and culture plate media commonly used in Strep A testing were evaluated for compatibility with the BD Veritor™ System for Rapid Detection of Group A Strep test. The effects of frozen storage of transport media samples on the stability of the antigen were evaluated in this study. The media tested were: Modified Amies, Modified Stuart's, Normal Saline and Phosphate Buffered Saline. The agar tested were Tryptic Soy Agar with 5% Sheep Blood and Selective Strep Agar.

Of the four media tested in this evaluation, all four demonstrated the expected results and met the acceptance criteria for both room temperature and overnight frozen storage conditions. Therefore, these four media are all compatible with the BD Group A Strep test. Although the media were non-interfering, dry swab transport and storage is recommended for testing with the BD Group A Strep test. Storage and transport of Strep A specimens in liquid transport will likely dilute the antigen while streaking on solid culture media may remove some organism from the swab, thus resulting in a lower number of bacteria introduced into the extraction reagent.

No interference was seen with the agar tested.

CLINICAL STUDIES

Performance characteristics for the BD Veritor™ System for Rapid Detection of Group A Strep were established in a multi-center clinical trial conducted at one clinical laboratory site and four POC sites during the 2011-2012 respiratory season. A total of 796 prospectively collected specimens were evaluated using the BD Veritor™ System for Rapid Detection of Group A Strep and bacterial culture. Throat swabs from symptomatic patient were obtained, 51.8% from females and 48.2% were from males. Specimens from patients five years old or younger comprised 39.1% of the total, with 59.3% from patients 6 to 21 years of age and 1.6% from patients 22 years of age or older.

The performance of the BD Veritor™ System for Rapid Detection of Group A Strep was determined by comparison to bacterial culture and is presented in the table below.

Clinical Performance Data			
	Culture		
Veritor	P	N	
P	144	29	*173*
N	5	618	*623*
	149	*647*	*796*
Reference Method: Culture Sensitivity: 96.6% (92.4%, 98.6%) Specificity: 95.5% (93.6%, 96.9%)			

Clinical Performance Data – By Site				
		Culture-Reference		
Site Code	Veritor	P	N	*Total*
Clinical Site	P	20	2	*22*
	N	0	82	*82*
Total		*20*	*84*	*104*
Reference Method: Culture-Reference Sensitivity: 100% (83.9%, 100%) Specificity: 97.6% (91.7%, 99.3%)				
POC 1	P	54	3	*57*
	N	5	188	*193*
Total		*59*	*191*	*250*
Reference Method: Culture-Reference Sensitivity: 91.5% (81.6%, 96.3%) Specificity: 98.4% (95.5%, 99.5%)				
POC 2	P	21	9	*30*
	N	0	111	*111*
Total		*21*	*120*	*141*
Reference Method: Culture-Reference Sensitivity: 100% (84.5%, 100%) Specificity: 92.5% (86.4%, 96.0%)				

Clinical Performance Data – By Site				
		Culture-Reference		
Site Code	Veritor	P	N	*Total*
POC 3	P	21	7	*28*
	N	0	106	*106*
Total		*21*	*113*	*134*
Reference Method: Culture-Reference Sensitivity: 100% (84.5%, 100%) Specificity: 93.8% (87.8%, 97.0%)				
POC 4	P	28	8	*36*
	N	0	131	*131*
Total		*28*	*139*	*167*
Reference Method: Culture-Reference Sensitivity: 100% (87.9%, 100%) Specificity: 94.2% (89.1%, 97.1%)				

Reproducibility

The reproducibility of the BD Veritor™ System for Rapid Detection of Group A Strep was evaluated at one clinical and two POC sites. The panel was composed of 4 simulated Group A Strep samples. These included high negative samples (i.e. samples containing a very low concentration of Group A Strep), a low positive sample (near the limit of detection), a moderate positive sample and a negative sample. The panel was tested by two operators at each site over five days. The results are summarized below.

BD Veritor™ Group A Strep Reproducibility				
Sample	**Site 1**	**Site 2**	**Site 3**	**Total**
High negative	3.3% (1/30) (0.6%, 16.7%)	0% (0/30) (0%, 11.3%)	0% (0/30) (0%, 11.3%)	1.1% (1/90) (0.2%, 6%)
Low positive	96.7% (29/30) (83.3%, 99.4%)	83.3% (25/30) (66.4%, 92.7%)	93.3% (28/30) (78.7%, 98.2%)	91.1% (82/90) (83.4% 95.4%)
Moderate positive	100% (30/30) (88.6%, 100%)	96.7% (29/30) (83.3%, 99.4%)	100% (30/30) (88.6%, 100%)	98.9% (89/90) (94%, 99.8%)

Negative	0% (0/30) (0%, 1.3%)	0% (0/30) (0%, 11.3%)	0% (0/30) (0%, 11.3%)	0% (0/90) (0%, 4.1%)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 6, 2013

Becton, Dickinson and Company
C/O Gregory Payne
Director, Quality Systems and Regulatory Affairs
10865 Road to the Cure, Suite 200
San Diego, CA 92121

Re: K122718
Trade/Device Name: BD Veritor™ System for Rapid Detection of Group A Strep
Regulation Number: 21 CFR 866. 3740
Regulation Name: *Streptococcus spp.* Serological Reagents
Regulatory Class: Class I
Product Code: GTY
Dated: January 17, 2013
Received: January 23, 2013

Dear Mr. Payne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Uwe Scherf for

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

510(k) Number: _k122718_____

Device Name: BD Veritor™ System for Rapid Detection of Group A Strep

Indications for Use:

The BD Veritor™ System for Rapid Detection of Group A Strep test is a rapid chromatographic immunoassay for the direct and qualitative detection of Group A Streptococcus antigen from throat swabs of symptomatic patients. It is intended to be used in conjunction with the BD Veritor™ System Reader as an aid in the diagnosis of Group A Strep. All negative test results should be confirmed by bacterial culture because negative results do not preclude Group A Strep infection and should not be used as the sole basis for treatment.

The BD Veritor System for rapid detection of Group A Strep test is intended for use in point-of-care or laboratory settings.

Prescription Use __√__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

CDR Raquel Peat, PhD

Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

510(k) K122718